



DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 10, 1999

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-17

Garry D. Shaw, President  
Cossack Caviar, Inc.  
6900 191<sup>st</sup> Place NE  
Arlington, Washington 98223

WARNING LETTER

Dear Mr. Shaw:

On January 27, 1999, a FDA Analyst conducted an inspection of your firm located at 6900 191<sup>st</sup> Place NE, Arlington, Washington. At the conclusion of the inspection, our analyst presented you a FORM FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of the FORM FDA 483 is enclosed for your review. By virtue of these deficiencies, the salmon roe processed at your facility is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. You did not identify all the necessary critical control points in your HACCP plan for caviar. Your HACCP plan was missing critical control points at the draining after brining, and the finished product storage steps to control bacterial pathogen growth and toxin formation, including *Clostridium botulinum* at the finished product storage step. Note that the finished product storage critical control point is not required when the caviar is frozen immediately after packing. Therefore, the HACCP plan does not meet the requirement of 21 CFR Part 123.6(c)(2).
2. You did not list appropriate critical limit(s) that must be met at the brining critical control point in your HACCP plan for caviar. You need to establish critical limit(s) to prevent, eliminate, or reduce to an acceptable level, the occurrence of food safety hazards associated with bacterial pathogens and their toxins, including *Clostridium botulinum* toxin formation. The FDA acknowledges your September 15, 1998 written response to the FORM FDA 483 issued on July 9, 1998 with respect to control of *Clostridium botulinum*. However, you have not demonstrated that the correlation between the monitoring of total percent salt is suitable for documenting that an adequate water-phase salt has been achieved. Therefore, the critical limit does not meet the requirement of 21 CFR Part 123.6(c)(3).

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3. The predetermined corrective action in your HACCP plan for caviar did not adequately describe the steps that are to be taken to ensure that no product enters commerce and the cause of the deviation is corrected. Additionally, you need to identify a person as responsible for ensuring corrective actions are taken when needed. Therefore, the predetermined corrective action(s) does not meet the requirement of 21 CFR Part 123.7(b).
4. Your firm was not maintaining sanitation monitoring records for the following three of eight areas of sanitation:
  - a. prevention of cross contamination;
  - b. proper labeling, storage, and use of toxic compounds; or
  - c. control of employees with adverse health conditions.
5. 21 CFR Part 123.11(c) requires you to maintain records of sanitation monitoring and any corrections made as a result of monitoring.
6. Your firm lacked verification procedures for salmon roe imported from Canada. 21 CFR Part 123.12(a)(2) requires you to ensure that the salmon roe was processed in accordance with the HACCP requirements. As part of verification, 21 CFR Part 123.12(a)(2)(i) requires product specifications that ensure the product is not adulterated under Section 402 of the Act because it may be injurious to health or have been processed under insanitary conditions. The second part of verification is to implement an affirmative step, as described under 21 CFR Part 123.12(a)(2)(ii).

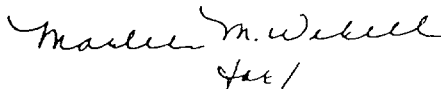
The FDA acknowledges your written response; however, we were not able to determine from your letter whether or not the corrections to your sanitation and import HACCP programs are adequate.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Garry D. Shaw, President  
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You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Handwritten signature of Roger L. Lowell in cursive script.

Roger L. Lowell  
District Director

Enclosures:  
FORM FDA 483  
21 CFR Part 123  
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement  
WSDA